MinXray P200D Mark III
PORTABLE DENTAL X-RAY UNIT

INSTALLATION AND OPERATING INSTRUCTIONS

This special purpose equipment is for portable dental radiography only.
It is not designed, nor does it meet, the Standards for any other use.

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INTRODUCTION

This manual provides information about the MinXray Model P200D Mark III Portable Dental X-ray Unit.

CARELESS OR IMPROPER USE OF X-RAY EQUIPMENT CAN BE EXTREMELY HAZARDOUS.
It is imperative that this equipment be operated and serviced only by trained personnel familiar with the safety precautions required to prevent excessive exposure to primary X-ray radiation, the dangers of exposure to X-ray radiation, and the proper use of the equipment discussed in this manual.

All personnel authorized to operate or service this equipment should be fully acquainted with the established maximum permissible doses, safety recommendations, and procedures derived from the following sources:

A. National Council on Radiation Protection Report No.33 (Medical X-Ray and Gamma Ray Protection for Energies up to 10 MEV - Equipment Design and Use); from NRCP Publications; P.O. Box 30175, Washington, D.C. 20014.

B. National Bureau of Standards Handbook No.76 (Medical X-Ray Protection up to Three Million Volts); from the Super8intendend of Documents, Government Printing Office, Washington, D.C. 20401.

C. All documents relating to the Performance Standard for Diagnostic X-Ray Systems, 21 CFR Subchaper J, Part 1020; obtainable from FDA Center for Devices and Radiological Health, Department of HHS, 2098 Gaither Road, Rockville, MD 20850.

D. State and local regulations governing radiation protection and the use of diagnostic X-ray equipment.

E. Requirements of the user's in-house radiation protection program.

F. Instructions and precautionary notices of this manual.

Although this equipment incorporates protective design features for limiting both the direct (primary) x-ray beam and the secondary radiation produced by this beam, design factors alone cannot prevent human carelessness, negligence, or lack of knowledge. This apparatus is sold with the understanding that the user assumes sole responsibility for radiation safety and that MinXray, Inc., its agent and representatives, do not accept any responsibility for:

A. Injury or danger to patient or other personnel from x-ray exposure.

B. Overexposure due to poor operating techniques or procedures.

C. Equipment not properly serviced or maintained in accordance with this manual.

D. Equipment which has been modified or tampered with in any way.

RECORDKEEPING REQUIREMENTS

1. Dealer and Distributor Records.

   a. Dealers and distributors of x-ray equipment shall obtain and preserve for a period of five years from the date of sale, award, or lease of each such product, such information as is necessary to permit tracing of specific products to specific purchasers.

   b. Such information shall include:
      1) The name and mailing address of distributor, dealer, or purchaser to whom the product was transferred.
      2) Identification and brand name of the product.
      3) Model number and serial or other identification number of the product.
      4) Date of sale, award or lease.

2. Records to be Furnished to MinXray, Inc., by Dealers and Distributors.

   The information required in "1" above shall immediately be forwarded to MinXray unless:

   a. The dealer or distributor elects to hold and preserve such information, and to immediately furnish it to MinXray, Inc., when advised by MinXray or Director, Department of Health and Human Services, that such information is required for purposes of Section 359 of the Radiation Control for Health and Safety Act of 1968.

   b. The dealer or distributor, upon making the election under "a" above of this section, promptly notifies MinXray and the Bureau of Radiological Health of such election. Such notification shall be in writing and shall identify the dealer or distributor and the type of equipment for which the information is being accumulated.

3. Assembler's Report.

   All assemblers who install certified components shall file a report of such assembly. All assemblers reports shall be on Form FD-2579, which is prescribed by and available from the Director. FDA/Department of Health and Human Services, Division of Compliance, 1390 Piccard Drive, Rockville, Maryland 20850. The original of Form FD-2579 sha11 be sent to the Director and copies to the purchaser, State Agency responsible for radiation protection, and one kept by the assembler for a period of least 5 years.

TO: ALL MANUFACTURERS AND ASSEMBLERS OF DIAGNOSTIC X-RAY EQUIPMENT

SUBJECT : Final Testing of Diagnostic X-ray Systems and Components Following Assembly.

This letter is intended to establish HHS policy relative to final testing of a newly-assembled x-ray system or component before release to the user.

Manufacturer Responsibility - The FDA believes that plant-based manufacturers must include in their assembly instructions a specific requirement that the assembler perform a test(s) for the applicable requirements of the FDA performance standard at the time of installation. A thorough explanation of the equipment required and step-by-step instructions must be provide by the component or system manufacturer. The instructions should include a requirement to record key data to demonstrate at a later data that all tests were performed and that the equipment was left in full compliance with the standard. The FDA's Department of Health and Human Services will insure that these assembler test instructions are provided through a close review of the information submitted by manufacturers in initial, model change and annual reports. Plant-based manufacturers who do not include a final compliance test in their assembler instructions could be subject to disapproval of their quality control and testing program.

Assembler Responsibility - Assemblers of diagnostic x-ray equipment must perform a test or tests for the applicable requirements of the FDA performance standard at the time of installation if specified in the assembly instructions provided by the component or system manufacturer. Assemblers who do not perform and document such final compliance tests will be considered by the FDA to have issued a false and misleading certification and will, therefore, be subject to regulatory action by the Agency.

Should they be any questions concerning this Bureau policy please call X-ray Products Branch at 301-427-1165.

MinXray P200D Mark III

INSTALLATION INSTRUCTIONS

UNPACKING:

The MinXray P200D Mark III portable x-ray unit consists of an x-ray tubehead and control, mounting handle, dental cone, exposure cord, power cord, and carrying case.

If a stand is purchased with the P200D Mark III, instructions for its assembly are included with the stand.

When the equipment is received each shipping container should be carefully examined for any evidence of mishandling during shipment. Note its condition, if abnormal, carefully unpack all parts and examine for damage. If any damage is noted, immediately report it to the carrier in the proper manner, by personally calling it to attention by phone where possible, and filing a written report.

All printed matter supplied with the P200D Mark III should be saved for reference during installation and operation.

ASSEMBLY INSTRUCTIONS:

1. Remove the x-ray tube head and control, cone, exposure cord and power cord from the carrying case.

2. Screw the cone on to the front of the tubehead.

3. Plug the exposure cord into the rear of the tubehead.

4. Plug the power cord into the rear of the tubehead.

5. Attach the assembled x-ray unit to a stand.

6. Check the line voltage and the voltage on the rating label;

   115V type of P200D Mark III requires line voltage between 110 and 130.
   230V type of P200D Mark III requires line voltage between 220 and 260.
   It must be with 15 ampere #12 three-wire service.
   (If it is not, the films may be light or show lack of sufficient penetration.)

7. Plug the power cord into the wall outlet.

The P200D Mark III is now assembled and ready for testing.

PRE-OPERATIONAL REQUIRED TESTING.

The following test is the responsibility of the dealer and must be conducted without fail. Fill out the check list for this report, when installation of x-ray unit is complete.

1, LV INDICATOR

TESTING THE LV INDICATOR

Test method:

Measure voltage of wall outlet, and confirm that the following conditions are fulfilled.

Wall outlet voltage

130~125V (260~250V)	Green LED goes on when LV knob turns 1 click clockwise.
125~120V (250~240V)	Green LED goes on when LV knob turns 2 click clockwise.
120~115V (240~230V)	Green LED goes on when LV knob turns 3 click clockwise.
115~110V (230~220V)	Green LED goes on when LV knob turns 4 click clockwise.
110~105V (220~210V)	Green LED goes on when LV knob turns 5 click clockwise.

If the LV indicator needs adjustment: (1) remove the 4 screws on the cover; (2)adjust the potentiometer "A" on the printed circuit board (see fig 1.) so that green LED goes on at the above settings; (3)replace the cover and the 4 screws.

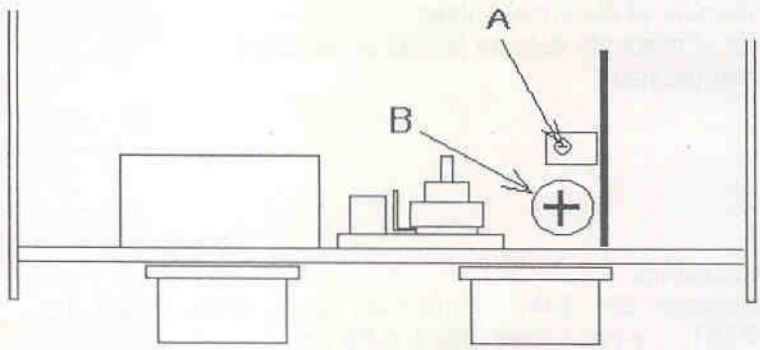


fig.1

2, TIMER

The electronic timer has a built-in lag of approximately 0.15 sec. Since the filament of the x-ray tube is off when the unit is not emitting radiation, it takes approximately 0.15 sec, for the x-ray tube filament to warm up before x-ray is emitted. When checking the timer with a cycle counter, 0.15sec must be added to the time set on the timer.

The timer has a filament warm-up time of 0.15 sec(9 electrical pulses) built into its settings, calculated as follows(see fig 2):

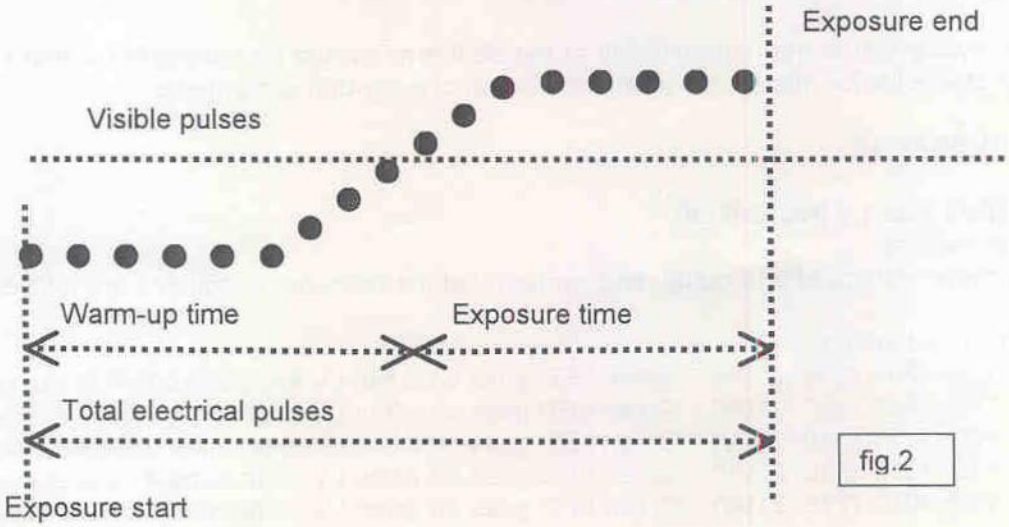


fig.2

TW = P – Dx

TW = Filament warm-up time
P = Total number of electrical pulses
Dx = Number of readable dots on film as determined by a spin top test

TESTING THE TIMER:

Test method:

2-1 Test method:

1. Set timer to 0.08 sec.
2. Set NERO as following settings.
   SID: 18 inches, wheel range: 50 ~ 85kV, sensitivity Low, phase select: 1Ø
   measurement mode: STAT x-ray values: 63kV, 0.08 sec.
3. Make exposure and read value of exposure time.
4. Measure value of exposure time at following settings with same procedure.
5. 0.08, 0.10, 0.20, 0.50, 1.00, 2.00 sec.

2-2 Instruments: NERO Model 6000M x-ray beam analyzer
Manufactured by Victoreen, Inc. or equivalent

2-3 Rejection limit:: ±2pulse(0.08 sec. ~ 0.2sec.), ±10%(0.25sec. ~ 2.0sec.)

If the timer needs adjustment: (1) remove the 4 screws on the cover; (2)adjust the potentiometer "B" on the printed circuit board(see fig 1.) so that radiation exposure time equals the time indicated on the timer dial, taking into consideration the accuracy tolerances;(3)replace the cover and the 4screws.

3.PEAK TUBE POTENTIAL

P200D Mark III has a filament warm-up time of 0.15 sec(9 electrical pulses) built into its settings. The kV is as follows.(see fig 3.) For that reason, measure kV with 0.15sec.delay time.

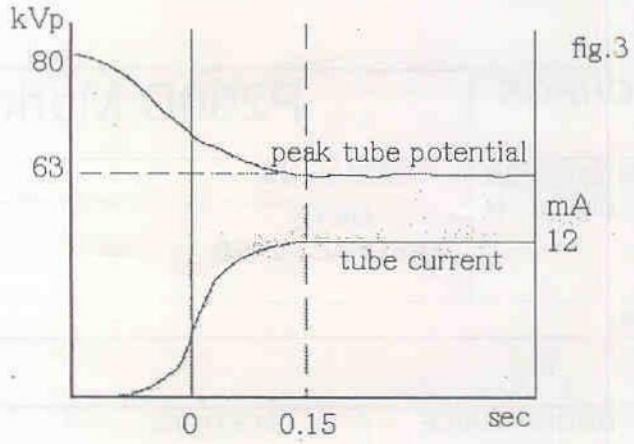


fig.3

Test method

3-1 Test method:

1. Set timer to 0.2 sec.
2. Set NERO as following settings.
   SID: 18 inches, wheel range: 50 ~ 85kV, sensitivity Hi, phase select:1ø measurement mode: SGL, time delay 0.1sec., x-ray values: 63kV, 0.2 sec.
3, Make exposure and measure value of avg.kV.
4,Measure value of avg.kV

3-2 Instruments: NERO Model 6000M x-ray beam analyzer
Manufactured by Victoreen, Inc. or equivalent

3-3 Rejection limit: 63kV±15%

4.TUBE CURRENT

P200D Mark III has a filament warm-up time of 0.15 sec(9 electrical pulses) built into its settings. The mA is as follows.(see fig 3.) For that reason, measure kV with 0.15sec.delay time.

Test method:

4-1 Test method:

1. Set timer to 2.0 sec.
2. Connect the DC-mA meter to the pin jack terminal on rear panel.
3, Make exposure and measure the mA value.
4,Measure Hi value of ch 2 at following kV settings, and timer to 2.0 sec. with same procedure.

4-2 Instruments: Portable Standard DC Ammeter Model 2011
Yokogawa Electric Works. Ltd. or equivalent.

4-3 Rejection limit: ±15%

INSTALLATION CHECK LIST

INSTALLATION CHECK LIST		P200D Mark III	
	Fill out this check list when installation is complete.	SERIAL NO.	
		DATE MANUFACTURED	
EQUIPMENT LOCATION			

TEST DESCRIPTION	ACCEPTANCE LIMITS	RESULTS	CHECK
Line Voltage	110~130V (220~260V)	V	☐ GO ☐ NO GO
Line Voltage Regulation	2~5%	.....%	☐ GO ☐ NO GO
Peak Tube Potential	63kVp±15%	.....kVp	☐ GO ☐ NO GO
Tube Current	12mA±15% 9.5mA±15%	.....mA .....mA	☐ GO ☐ NO GO
Exposure Time	0.08sec ±2pulse 0.1sec ±2pulse 0.2sec ±2pulse 0.5sec ±10% 1.0sec ±10% 2.0sec ±10%	.....sec .....sec .....sec .....sec .....sec .....sec .....sec	☐ GO ☐ NO GO
All Mechanical Movement	Smooth Movement		☐ GO ☐ NO GO
All Operation	See operation Manual		☐ GO ☐ NO GO

Instruments Used	Manufacturer	Model	Accuracy	Last calibrated

Dealer Name	Dealer Phone Number
Dealer Address	
Assembler signature	Date
Comments	

OPERATION INSTRUCTIONS

IT IS ASSUMED BY THE DISTRIBUTORS AND MANUFACTURER OF THE EQUIPMENT THAT THE PERSON RESPONSIBLE FOR ITS OPERATION HAS A GENERAL KNOWLEDGE OF THE USE OF X-RAYS, INCLUDING THE PRECAUTIONS WHICH MUST BE TAKEN.

****

OPERATION:

1. Position the tubehead for the radiograph desired.

2. Line voltage compensation. Turn the LV knob clockwise until the center green LED lights. The green LED must be lit before each exposure.

3. Radiology

   a. After positioning the patient and adjusting the line voltage compensator, set the electronic timer for the desired time. The technique chart following can be used as a guide.

   b. Stand as far as possible from the x-ray unit, press the exposure switch to initiate the exposure, and keep it pressed for the duration of the exposure. During exposure the "x-ray" light on the x-ray unit will go on and there will be an audible signal from the x-ray unit.

   c. The timer will automatically recycle; e.g. successive exposures can be made at the previously set time by merely pressing the exposure button.

   d. An exposure can be interrupted at any time by releasing the exposure button.

   e. When an exposure is terminated, the "x-ray" light goes out and the audible signal ends.

Note: Confirm the wall outlet voltage and the voltage on the rating label of the P200D Mark III, before connecting the power cord.

SAFETY PRECAUTIONS:

1. During exposure the operator must stand as far as possible from the patient being x-rayed, and should wear a lead apron or stand behind a lead shield.

2. The operator must not stand in the primary x-ray beam.

3. The operator must wear a monitoring badge while operating this unit. It should be on the collar, and not on an area covered by a lead apron.

4. X-ray exposure should be kept as short as possible.

MAINTENANCE: The following must be checked at least every 6 months.

1. Tubehead

   a. Make sure the certification and identification labels are in place.

   b. Check for any loose or missing screws.

   c. Check for oil leaks.

   d. Check for any physical damage.

   e. Check the LV knob for proper operation.

   f. Check the timer for proper operation.

   g. Check all the cord connections.

   h. Check the exposure button; the exposure must terminate if the button is released during and exposure.

2. Beam Limiting Device (cone)

   a. Make sure the certification label is on the cone.

   b. Check for any physical damage.

3. Indicators

   a. Make sure the green light goes on when the LV knob is turned to the right from the off position.

   b. Check the x-ray "ON" light for proper operation.

   c. Make sure the audible signal operates during an exposure.

TECHNIQUE CHART

Exposure time and angulation of central ray

		Exposure time (sec)		Angle
		Adult	Child	
Maxillary	Molars	0.8	0.5	+ 20°
	Biscupids	0.8		+ 30°
	Cuspids	0.6	0.4	+ 45°
	Incisors	0.6	0.3	+40°
Mandibular	Molars	0.6	0.4	- 5°
	Biscucpids	0.6		- 10°
	Cuspids	0.4	0.3	- 20°
	Incisors	0.4	0.3	- 15°
Maxillary Ccclusals	Incisor Region	1.0		+65°
	Cuspid-Molar Region	1.0		+.60°
Maxillary Occlusals	Incisor Region	1.0		- 55°
	Cuspid-Molar Region	1.0		- 90°
Note	KODAK Ultra-Speed film			
	Exposure times are intended as guides only. They are based on averages and may be modified to suit the individual patient. The increase or decrease should be made in steps of 20-25%.			

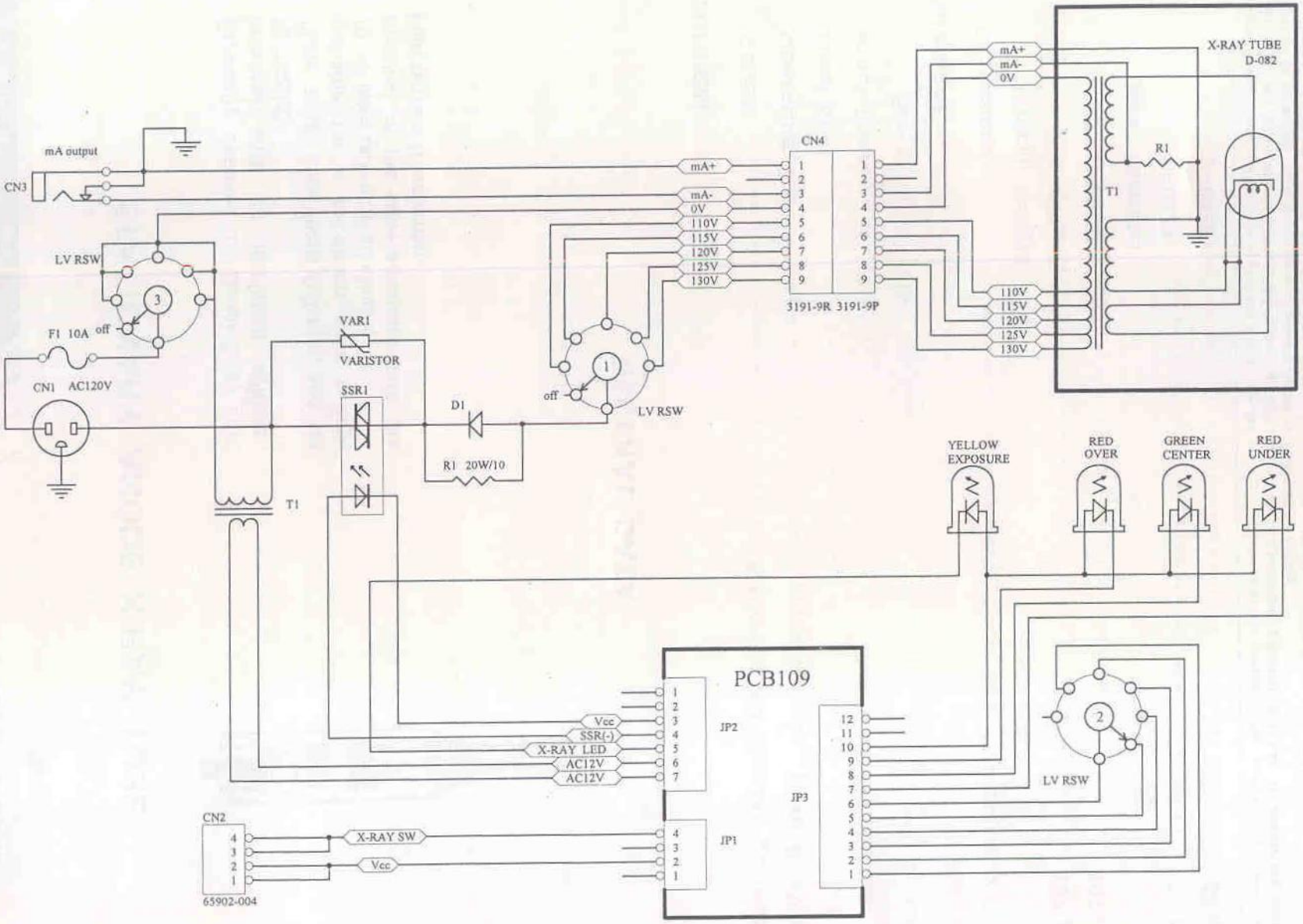
GENERAL INFORMATION

Maximum peak tube potential: Measurements taken with NERO M6000 X-ray beam analyzer.	63 kVp ± 15%
Leakage technique factors:	63 kVp 12 mA 2 sec.
Range of line voltage regulator:	110 - 130V AC(220 - 260V AC), 50/60 Hz.
Current at 12 mA, 63 kVp output:	6 amps

Line voltage regulation: 2 ~ 5 %

The stated mA and line current are under conditions of input line voltage of 110 - 130V (220 - 260V) with 2 ~ 5% regulation. If regulation is less, the amps drawn and mA can be higher than stated.

Generator rating:	12 mA at 63kVp ± 15%
mA measured with a precise DC mA meter across points N and NE of the high tension transformer (see schematic diagram). Input is 117V AC (230V AC), 50/60 Hz. Tolerance is ± 15%.	
Duty cycle:	30 : 1
Maximum deviation from fixed factors:	± 15%
X-ray tube:	Type D-082B Manufactured by Toshiba



P200D Mark III

STATIONARY ANODE X-RAY TUBE

- Especially designed for dental X-ray unit.
- Provided with an insulation cylinder. (D-082BS)
- These tubes have focus 0.8 mm, and are available for a maximum tube voltage 70 kV with self-rectified circuit.
- Installed in the same enclosure with the high tension transformer.

GENERAL DATA

ELECTRICAL:

Circuit ..... Self-rectified (Center-grounded)

Operating Tube Voltage ..... 50 to 70 kV Max

Focal Spot ..... 0.8 mm

Input Energy (at 1.0 s) :

See rating charts. ..... 600 W

MECHANICAL:

Dimensions ..... See dimensional outline.

Overall Length:

D-082B ..... 102 mm

D-082BS ..... 107 mm

Max. Diameter:

D-082B ..... 31 mm

D-082BS ..... 38 mm

★ The information contained herein is presented only as a guide for the applications of our products. No responsibility is assumed by TOSHIBA for any infringements of patents or other rights of the third parties which may result from its use. No license is granted by implication or otherwise under any patent or patent rights of TOSHIBA or others.
★ The information contained herein may be changed without prior notice. It is therefore advisable to contact TOSHIBA before proceeding with the design of equipment incorporating this product.

Target Angle		20 degrees
Inherent Filtration		At least 0.8mm Al equivalent at 50 kV
X-ray Coverage		354 x 354 mm at SID 490 mm
Weight (Approx.):		
	D-082B	95 g
	D-082BS	185 g
Cooling Method		Oil immersed (60°C Max) and convection oil cooling
Tube Holding	D-082B	Holding the glass envelope of the anode end and cathode end, or the screw of the anode shank
	D-082BS	Holding the insulation cylinder

MAXIMUM AND MINIMUM RATINGS

(At anytime, these values must not be exceeded.)

Max. Tube Voltage	70 kV
Max. Inverse Tube Voltage	80 kV
Min. Tube Voltage	50 kV
Max. Tube Current	
See rating charts.	19 mA
Max. Filament Current :	2.0 A
Filament Voltage :	
At max. filament current	2.9 to 4.0 V
Thermal Characteristics :	
Anode Heat Storage Capacity	7 kJ (10 kHU)
Max. Anode Heat Dissipation Rate	210 W (300 HU/s)

CAUTIONS

Read through this page before using the tube.

Since X-Ray tube will emit x-rays when it is energized with high voltage, special knowledge is required to handle it. The items below show general cautions for the tube.

1. The tube shall be handled or operated only by qualified personnel. Only specialist who has good knowledge of X-Ray tube should assemble, maintain and remove the tube.

2. The tube envelope is made of glass. In transporting and handling, sufficient care should be taken not to give strong impact or vibration to the tube.

3. Radiation protection of the tube unit assembled with this tube must be sufficiently taken the troubles. And the leakage technique factor of the tube unit must not exceed the maximum anode cooling rate of this tube.

4. Regulations and standards require the minimum source-skin distance (SSD) and the minimum filtration of the useful beam. Use the tube after fulfilling them.

5. The tube might be broken due to only one overload operation. Provide proper overload protection circuit. Operate the tube by selecting a proper input condition according to the conditions for operation and tube characteristics charts.

6. If any abnormality is found in using this tube, immediately cut off the power supply and contact TOSHIBA service department.

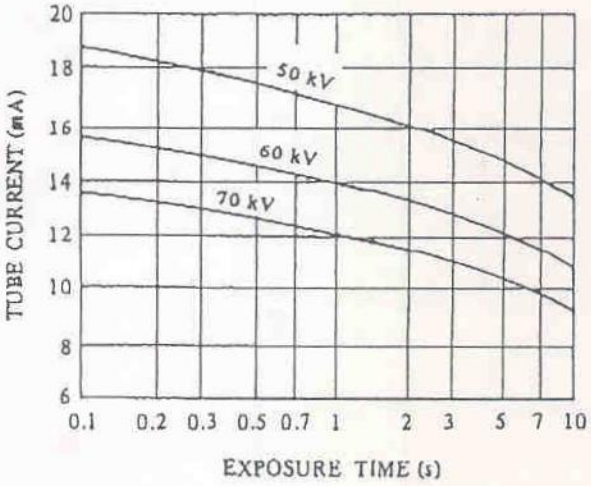
7. The charts of these data sheets are indicating standard values.

8. For usage not described here or for any unclear items, contact TOSHIBA service department.

MAXIMUM RATING CHARTS (ABSOLUTE MAXIMUM RATING CHARTS)

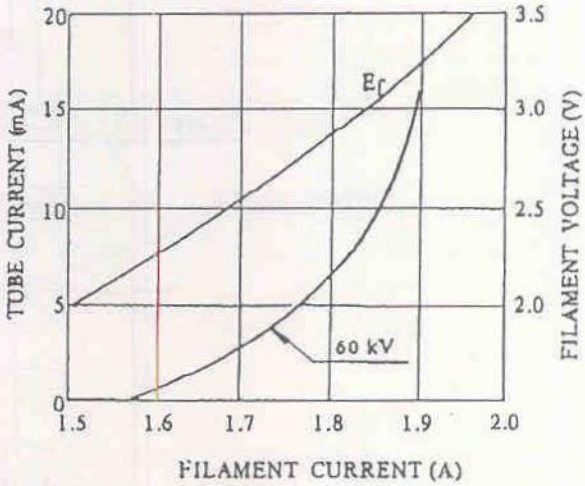
SELF-RECTIFIED

FOCAL SPOT: 0.8 mm

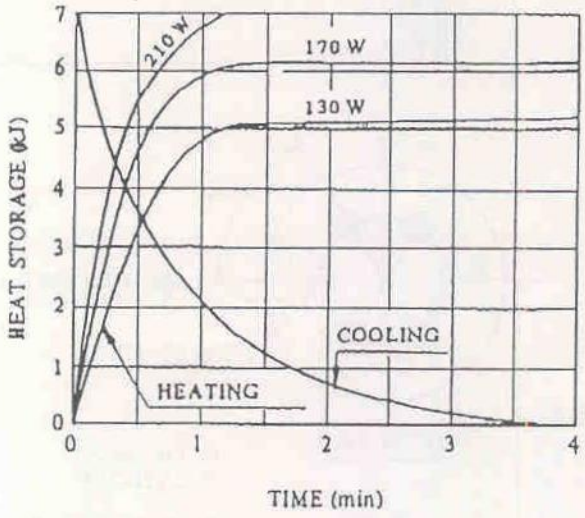


EMISSION & FILAMENT CHARACTERISTICS

SELF-RECTIFIED

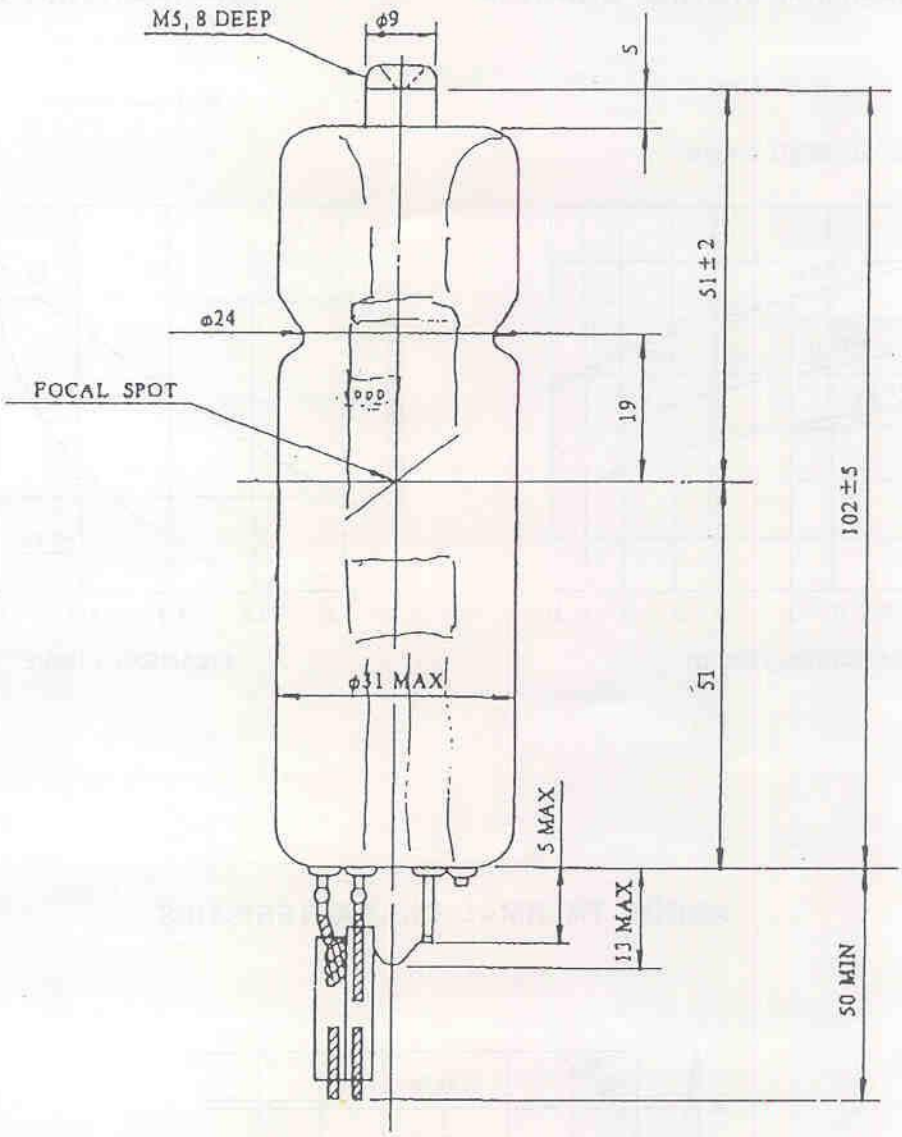


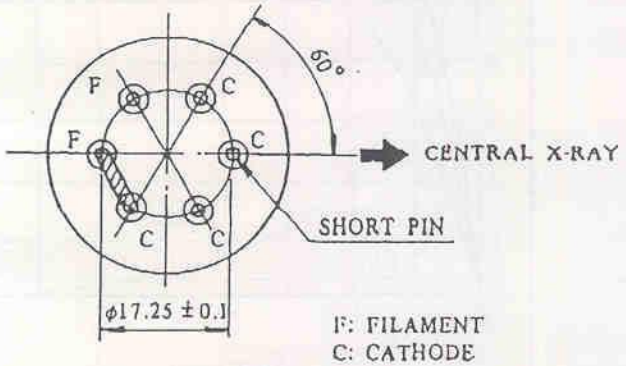
ANODE THERMAL CHARACTERISTICS



DIMENSIONAL OUTLINE

Unit mm





F: FILAMENT
C: CATHODE

Terminals "C" are connected mutually inside the tube.